REMARKS/ARGUMENTS

The Office is requiring restriction to one of the following groups:

Group I: Claims 1-3, drawn to an anti-brain-derived neurotrophic factor (BDNF) antibody;

Group II: Claims 4-6, drawn to a diagnostic kit comprising an anti-BDNF antibody and a labeling agent;

Group III: Claims 7-10, drawn to a method for assessing risk of an ischemic heart disease comprising measuring BDNF concentration in blood;

Group IV: Claim 11, drawn to a therapeutic drug comprising a compound that increases BDNF;

Group V: Claim 12 and 17, drawn to a therapeutic drug comprising BDNF;

Group VI: Claims 13, drawn to the use of a compound that increases BDNF in the production of a therapeutic drug for ischemic heart disease;

Group VII: Claim 14, drawn to the use of BDNF in the production of a therapeutic drug for ischemic heart disease;

Group VIII: Claim 15, drawn to a method for treating ischemic heart disease comprising administering a compound that increases BDNF;

Group IX: Claim 16, drawn to a method for treating ischmic heart disease comprising administering BDNF;

Group X: Claim 18, drawn to use of BDNF for the production of a drug that prevents post-infarction myocardial remodeling, and

Group XI: Claim 19, drawn to a method for suppressing/preventing post-infarction myocardial remodeling comprising administering BDNF.

Applicants elect, with traverse, Group III, Claims 7-10 for examination.

Restriction is only proper if the claims of the restricted groups are independent or patentably distinct and there would be a serious burden placed on the Examiner if restriction is not required (MPEP §803). The burden is on the Examiner to provide reasons and/or examples to support any conclusion in regard to patentable distinction (MPEP §803). Moreover, when citing lack of unity of invention in a national stage application, the Examiner has the burden of explaining why each group lacks unity with each other group specifically describing special technical features in each group (MPEP § 1893.03(d)).

The Office has alleged that Groups I-XI lack unity of invention because the groups do not share the same or corresponding technical feature and that Groups I-XI lack unity of invention because they do not share a special technical feature in view of Rosenfeld et al., Protein Expression and Purification, 6(4): 465-471, August 1996.

However, Annex B of the Administrative Instructions under the PCT at (b) Technical Relationship states:

> "The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that defines a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any)."

Applicants respectfully submit that the Office has not provided any indication that the contents of the claims interpreted in light of the description was considered in making the assertion of a lack of unity and therefore has not met the burden necessary to support the assertion.

In addition, The MPEP §806.03 states:

> "Where the claims of an application define the same essential characteristics of a *single* disclosed embodiment of an invention, restriction therebetween should never be required. This is because the claims are not directed to distinct inventions; rather they are different definitions of the same disclosed subject matter, varying in breadth or scope of definition."

Applicants respectfully submit that the Office has not considered the relationship of the inventions of Groups I-XI with respect to MPEP §806.03 nor paragraph (b) of Annex B of the Administrative Instructions Under the PCT. Therefore the burden necessary according to MPEP § 1893.03(d) to sustain the conclusion that the groups lack of unity of invention has not been met.

Additionally, citing MPEP 806.05(j), the Office has characterized that: the Groups I, II, IV and V are directed to related products, stating that: "[I]n the instant case, the inventions as claimed are each structurally distinct"; the Groups III and VI-XI are directed to related processes, stating that "[I]n the instant case, the inventions as claims are directed to different

methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions."

However, the MPEP §806.05(j) states that related product inventions are distinct if:

> "(A) the inventions *as claimed* do not overlap in scope, i.e., are mutually exclusive;
> (B) the inventions *as claimed* are not obvious variants; and
> (C) the inventions *as claimed* are either not capable of use together or can have a materially different design, mode of operation, function, or effect."

Applicants respectfully submit that the Office has not adequately demonstrated any of the indications of distinctness (A), (B) or (C) listed in MPEP (§806.05(j)) for any of the groupings cited. Moreover, there is no evidence of record to show that the claimed inventions can be used as the Office has alleged and the Office has provided no examples in support of the conclusion. The Office has simply stated the conclusion.

The Office has further characterized the relationships of Groups IV and VIII as related as product and process of use. Citing MPEP 806.05(h) the Office has stated, "In the instant case the compound, as claimed, can be used in a materially distinct method such as in the manufacture of a drug (Group VI)".

The MPEP §806.05(h) states:

> "A product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process.
> The burden is on the Examiner to provide an example, . . ."

However, there is no evidence of record to show that the claimed product can be used as the Office has alleged and the Office has provided no examples in support of the conclusion. The Office has simply stated the conclusion.

Accordingly, and for the reasons presented above, Applicants submit that the Office has failed to meet the burden necessary in order to sustain the requirement for restriction. Applicants therefore request that the requirement for restriction be withdrawn.

Applicants respectfully submit that the above-identified application is now in condition for examination on the merits, and early notice thereof is earnestly solicited.

Respectfully Submitted,

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